Bassachusetts General Hospital Founding Member, Mass General Brigham

Adalimumab - Medication Information

What is adalimumab pegol?

Adalimumab is a medication used to treat Crohn's disease and ulcerative colitis. It is in a class of medications called anti-TNFs, which are immunosuppressants that slow down the immune system's activity to heal inflammation.

They are available as:

- Original ("brand name"): Humira®
- Biosimilars: Amjevita[™], Hadlima[™], Hadlima[™] CF, Cyltezo[®], Yusimry[™], Hulio[™], Hyrimoz[™], and Idacio[®]

Biosimilars are medications that are very similar to the original medication. They are FDA-approved, made from the same types of sources, and just as safe and effective as the original medication.

How is adalimumab given?

Adalimumab is an injection, or shot, that you can give yourself subcutaneously (just under the skin). They come either as an auto-injector pen or as a pre-filled syringe with a needle. Both are equally effective. They are usually given on your thighs or stomach area. An IBD nurse or pharmacist will show you how to do the injections at your first appointment.

The first dose is given as 160 mg (2 to 4 pens total, depending on which biosimilar you have). Two weeks later, you will be given 80 mg (1 to 2 pens total, depending on which biosimilar you have). After that, 40 mg (1 pen) will be given every 2 weeks. About half of patients will need 40 mg every week. Your provider will work with you to develop an injection schedule that works best for your specific disease.

When can I expect adalimumab to work?

Many patients start to feel an improvement in symptoms within 1-2 weeks of starting adalimumab. Typically, up to 6 weeks is required to see a benefit.

Adalimumab works for most patients. The medication may stop working in up to 10% (1 in 10) of patients every year. To make sure that it keeps working, it is important to stay on track with your injection schedule and do not miss any injections. In some cases, your doctor may also have you start a second immunosuppressive medication along with adalimumab to help it work better and remain effective longer.

Studies have shown that early effective treatment for Crohn's disease or ulcerative colitis is associated with long-term benefits including lowering the likelihood of needing surgery or hospitalization related to these conditions.

What tests are needed while I am on adalimumab?

Before beginning adalimumab treatment, you will need blood tests to check for hepatitis B and tuberculosis infections. You may also need to test for tuberculosis every year. Blood counts and liver tests are done every 4 months while on adalimumab. At times, your doctor may also check your adalimumab level to make sure the dose is working well for you.

What are the potential side effects related to adalimumab?

Side effects with adalimumab may include:

Allergic reaction: Patients may develop allergic reactions to adalimumab as with any other medication. Reactions may include rash, hives, or swelling of the lips or throat. This is uncommon and can be treated with steroid and antihistamine medications.



Injection site reaction: A small number of patients may develop an injection site reaction such as pain, redness, or swelling where the injection was given. This usually goes away within 2-3 days after each injection and sometimes can be treated with antihistamine medications.

Infection: As with other medications that act on the immune system, adalimumab can increase your risk of infections. Serious infections are uncommon, but serious medical conditions like uncontrolled diabetes or lung disease may increase this risk.

Lymphoma: Adalimumab can also increase the risk of lymphoma, a form of cancer of the lymph node. In the general population, about 2 out of 10,000 people get diagnosed with lymphoma every year. With adalimumab, this risk may increase to 3-4 out of 10,000 people.

Opposite immune reaction: Rarely, adalimumab may cause an opposite immune reaction such as psoriasis or lupus. These occur in 1-3% (1-3 in 100) of patients.

Skin cancer: Adalimumab may also increase the risk for skin cancer. This is rare, but taking proper precautions to lower skin cancer risk is recommended such as wearing protective clothing, applying sunscreen, and avoiding being outside for extended periods of time when the UV index is high.

Medical history: Individuals with demyelinating diseases (like multiple sclerosis or optic neuritis), active cancer, history of skin cancer, or history of congestive heart failure should discuss the safety of adalimumab with their gastroenterologist (GI doctor).

Please see the medication package insert for the full list of potential side effects.

Is adalimumab safe during pregnancy and breastfeeding?

Women and men on adalimumab have not been associated with fertility problems, miscarriages, birth defects, preterm births, stillbirths, or other pregnancy-related problems. Most patients continue the adalimumab treatment during their pregnancy. You may get your last dose of adalimumab early in the third trimester of your pregnancy. If you are on adalimumab while pregnancy, live virus vaccines such as the rotavirus vaccine are not recommended for your baby within the first 6 months of age. Speak with your baby's pediatrician about the risks and benefits of a live vaccine for your baby. It is safe to breastfeed while on adalimumab. This has not been shown to have any negative impacts on the baby.

It is important to discuss with your provider about continuing adalimumab before, during, and after pregnancy.

How can I take care of my health while on adalimumab?

It is important to be up to date with your health maintenance while on adalimumab. This includes being current on all the recommended vaccines such as the flu, COVID-19, pneumococcal, and shingles vaccines. You should not get any live virus vaccines while on adalimumab or for 3 months after stopping it.

It is also important to be up to date in your general cancer screening including mammograms and pap smears for women, and skin check-ups for both men and women.

Speak to your primary care doctor about whether you are up to date on all your vaccines and cancer screening.



What if my out-of-pocket costs are high with this treatment?

Our pharmacy team will work with you to see if you qualify for patient assistance and help with the application process.

The manufacturers of adalimumab have patient assistance programs for patients on the medication. To learn more, visit the manufacturer's website for your medication:

- Humira: <u>humira.com/humira-complete</u>
- Amjevita: <u>amjevita.com/supportplus/financial-support</u>
- Hadlima or Hadlima CF: <u>hadlima.com/co-pay-assistance-enrollment</u>
- Cyltezo: pro.boehringer-ingelheim.com/us/products/cyltezo/savings-and-support
- Yusimry: <u>yusimry.com/starting-yusimry</u>
- Hulio: <u>hulio.proxe360.net</u>
- Hyrimoz: <u>portal.trialcard.com/sandoz/hyrimoz</u>
- Idacio: kabicare.us/hcp/program/idacio-adalimumab-aacf/how-to-enroll

What if I have questions about adalimumab?

Talk with your provider about any questions or concerns you may have about adalimumab.

This document has been reviewed for plain language by Blum Center staff.

